

REMARKS

The non-final Office Action was issued on pending claims 16-50. Claims 16-38 stand rejected and claims 39-50 were withdrawn from consideration. In this Response, no claims have been amended, cancelled or added. Thus, claims 16-38 are pending and under consideration and claims 39-50 are pending and withdrawn from consideration.

Applicant invites the Examiner to call Applicant's Representative to discuss any issues with this application.

Claim Rejections – 35 U.S.C. § 103

In Office Action paragraph 4, claims 16-17, 24, 27, 30-32, 34 and 36-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Baldini et al.* (US 4,656,813) in view of *Ivey* (US 5,976,299). In Office Action paragraph 5, claims 18-20, 28-29 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Baldini et al.* in view of *Ivey* and further in view of *Duffey et al.* (US 5,129,212). In Office Action paragraph 6, claims 21-22 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Baldini et al.* in view of *Ivey* and *Duffy et al.* and further in view of *Madsen* (US 3,451,403). In Office Action paragraph 7, claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Baldini et al.* in view of *Ivey* and further in view of *Ogata* (GB 2142282 A). In Office Action paragraph 8, claims 25-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Baldini et al.* in view of *Ivey* and further in view of *Brennan et al.* (US 4,587,793). In Office Action paragraph 9, claim 33 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Baldini et al.* in view of *Ivey* and further in view of *Aindow et al.* (US 5,934,043). Applicant respectfully disagrees.

All of the claim rejections rely on *Ivey* (US 5,976,299). *Ivey* has a § 102(e) prior art date of June 30, 1997. The present application claims foreign priority based on Italian Application No. MI 96A 002451 filed November 22, 1996. More specifically, the present application is a continuation of US Application Serial No. 09/316,165 filed May 21, 1999, which is a continuation of International Application No. PCT/IB97/01458 filed November 18, 1997, which claims priority from Italian Application No. MI 96A 002451 filed November 22, 1996. A certified copy of the Italian priority document was submitted in the International Application. Enclosed is an English language translation of a certified copy of the priority document with a

statement that the translation is a true translation (accurate). Accordingly, Applicant is entitled to rely on the November 22, 1996 foreign priority filing date in Italy under 37 C.F.R. § 1.55.

Applicant's Italian priority date of November 22, 1996 predates the § 102(e) prior art date of June 30, 1997 for *Ivey*. Accordingly, *Ivey* is not prior art to the present application.

Thus, Applicant respectfully submits that the § 103 rejections have been overcome.

CONCLUSION

For the foregoing reasons, Applicant submits that the patent application is in condition for allowance and requests a Notice of Allowance be issued.

Respectfully submitted,

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VERIFICATION OF TRANSLATION

BAXTER - DEERFIELD

APR 8 2002

MEDICATION DELIVERY
PATENTS

I Guido MODIANO

of Via Meravigli, 16 - 20123 MILANO - ITALY

am the translator of the English language document attached
hereto and I state that said document is a true translation
of the Certified Copy of :

Italian Patent Application

N. MI96A002451

of November 22, 1996

This 4th day of April 2002

Signature of the translator



MINISTRY OF INDUSTRY, COMMERCE AND HANDICRAFT
GENERAL DIRECTORATE OF INDUSTRIAL PRODUCTION
CENTRAL PATENT OFFICE

(Seal of the Patent Office)

Authentication of a copy of documents concerning
the Industrial Invention Patent Application
No. MI96A002451

It is stated that the attached copy is in
conformity with the original documents as
filed with the application specified above,
whose data appear in the enclosed filing
certificate.

ROME, _____

THE DIRECTOR OF THE DEPARTMENT

(signature)

MINISTRY OF INDUSTRY COMMERCE AND HANDICRAFT

FORM A

ITALIAN PATENT AND TRADEMARK OFFICE - ROME

PATENT APPLICATION FOR AN INDUSTRIAL INVENTION, FILING OF RESERVES, ADVANCED ACCESSIBILITY TO THE PUBLIC

A. APPLICANT(S):

1) Name : BIEFFE MEDITAL S.p.A.
 Residence : Via Nuova Provinciale - 23034 Grosotto (SO)
 Code : 00615820149
 Name :
 Residence :
 Code :

B. APPLICANT'S REPRESENTATIVE C/O THE ITALIAN PATENT AND TRADEMARK OFFICE:

Surname, name : Dr. Ing. Italo Incollingo
 Fiscal code :
 Name of the Office to which he belongs: TOP PATENTS
 Via: Piazzale LAVATER No.: 3 City: MILANO Zip code: 20129 Prov.: MI

C. DOMICILED BY ELECTION C/O: see above

Via: No.: City: Zip Code: Prov.:

D. TITLE Proposed class (section, class, underclass) Group, undergroup

SYSTEM TO FORM, FILL AND SEAL FLEXIBLE BAGS

Advanced accessibility to the public: YES NO ☒ If petition: Date Reg. No.

E. INVENTORS:

Surname, Name	Surname, name
1) Alberto SICCARDI	3)
2)	4)

F. PRIORITY:

Country or organization Type of priority Appln. No. Filing Date enclosed S/R
 1)
 2)

Cancellation of reserves
 Date Docket No.

G. QUALIFIED CULTIVATION COLLECTION CENTRE FOR MICROORGANISMS

Denomination:

H. PARTICULAR ANNOTATIONS:**ATTACHED DOCUMENTS:**

Doc. 1) 1 ex. PROV. n. pages 13 abstract with main drawing, specification and claims (1 ex. Compulsory)
 Doc. 2) 1 ex. PROV. n. sheets 7 drawing (compulsory if cited in specification - 1 ex.)
 Doc. 3) 1 ex. RES. Letter of attorney
 Doc. 4) 1 ex. RES. Inventor's designation
 Doc. 5) RES. Priority documents with Italian translation
 Doc. 6) RES. Authorization or Assignment deed
 Doc. 7) RES. Complete name of Applicant

Cancellation of reserves
 Date Docket No.
 Compare single priorities

8) Payment receipt of Lit. 365.000.=

(compulsory)

Filled in on November 21st, 1996 APPLICANT(S) SIGNATURE Dr. Ing. Italo Incollingo

It continues YES/NO: NO

For the present deed a certified copy is requested YES/NO: NO

PROVINCIAL OFFICE OF INDUSTRY, COMMERCE AND HANDICRAFT OF MILANO Code 15

FILING RECORD: APPLICATION NUMBER MI96A002451 Reg. A

In the year 1996 on the 22nd of the month of November the above-mentioned Applicant(s) has(have) presented to me undersigned the present Application, consisting of n. 00 additional sheets for granting the above-mentioned patent.

I. VARIOUS ANNOTATIONS ON THE PART OF THE RECORDING OFFICER:

The Depositor

Office Seal

The Recording Officer

(signature)

(signature)

FORM A

ABSTRACT OF THE INVENTION WITH MAIN DRAWING, SPECIFICATION AND CLAIM

APPLN. NUMBER
PATENT NUMBER

REG. A

FILING DATE
ISSUE DATE

D. TITLE

SYSTEM TO FORM, FILL AND SEAL FLEXIBLE BAGS

L. ABSTRACT

In the system to form, fill and seal (FFS) flexible bags substantially according to Patent US-A 4,456, 813 (EP-A 142.758) use is now made of: - a total printing of the film as it winds off the supply reel; - a dry cleaning; - a gimballed aligning for the folding of the printed and washed film; - a hot-bar welding of the folded film; - a valve welding controlled by an algorithm; - a humidification treatment of the valve cavity; - a shaping of the bags by hot tools also controlled by an algorithm; - and a high precision dosage of the filling liquid.

DESCRIPTION

of an Application for an industrial invention patent
entitled: " SYSTEM TO FORM, FILL AND SEAL FLEXIBLE BAGS"
in the name of: BIEFFE MEDITAL S.p.A., at Grosotto (SO)
Inventor: Alberto SICCARDI

The present invention concerns a system to form, fill and seal (F.F.S.) containers of flexible plastic materials, in particular sterilizable bags containing solutions for administration, types of infusion solutions including at least phases consisting of:

- feeding from at least one reel B a plastic and flexible material in the form of a film or pellicle F, preferably multilayer, forming the bag;
- printing the said material pulled from the said reel;
- winding the said printed material FST;
- washing the printed material;
- aligning and folding the said printed and washed film FSTL;
- welding the folded film in a first direction;
- feeding and applying valves on the surface of the folded and welded film;
- making a second welding in a second direction;
- cooling and cutting the bags to send to them for overwrapping and sterilizing.

Numerous systems for manufacturing flexible containers and filling them with liquids; for instance, US Patent 4,456,813 discloses a particular

material of three laminated layers, a specific type of valve and a very generic "form and fill" system. However only in the US patent N° 4,456,813 (corresponding to the European patent N° 142,758) of the Applicant is there described a first efficient system, substantially automatic, for the industrial production of bags with valves, comprising the phases described in the introduction of this description and in the preamble of claim 1. This system has, for quite some time, permitted the achievement of large industrial targets; nevertheless, with all its merits, it has shown some limits or wrinkles. For example present day demands and the even more severe requirements imposed by the Health Authorities call for several further means such as the application of a means for bag suspension, the fixing of complex valves of the last generation, single or double (twin-valve) (e.g. of the type called VEM or EMO-LUER). These and other valves can have zones difficult to access, e.g. cavities that would require extremely long sterilization times for safe sterilization, compared with those needed to sterilize the bag: though, for example, this latter can be done satisfactorily in about 10 minutes in an autoclave at 120° C, that of the valves requires much

longer times that are not industrially acceptable. In fact the water would reach the cavities either through permeability of the bag wall on which the valve is welded, or through the external surfaces of the valve itself. If the volume of the cavity is small the danger is small but if the volume is big the danger is prohibitive.

In addition to long times there would always be uncertainty about the effectiveness of the treatment. Furthermore in the conventional system there were several difficulties in the sanitation of the various mechanisms, for example that of dosing. To dose the quantity of solution to fill the bag needed time that was certainly not short and was without adequate precision.

The first aim of the present invention is to provide a very advanced system (of the last generation) that does not have the disadvantages of previous systems and is characterized by high efficiency, reliability, hygiene security and maximum precision. Another aim of the invention is to provide the previous system with more efficient, less expensive and more compact treatment means. These and other aims are obtained in the system with the present invention, whose main characteristics are stated in the claims below, to which the reader is referred.

The different aspects and advantages of the invention will be seen better in the following description of the forms of realization (illustrative and not limiting) shown in the accompanying figures, where:

- fig. 1 is a block diagram of the process at the base of the system;
- fig. 2 is a planar representation of a first kinematics scheme of the realization of the process of fig. 1;
- fig. 2A is the enlarged representation of a variant of a portion of fig. 2;
- fig. 2B and 2C are two views in partial and schematic perspective of a dry cleaning means;
- fig. 3 is a schematic and partial axonometric view that shows a preferred arrangement of the stages and means for the realization of the process in fig. 1;
- figs 4 and 5 are two frontal views, partially in section, of two valves;
- figs 6 and 7 are schematic top views of bags with the valves of figs 4 and 5 and with a ring AS in the suspension hole FOS;
- fig. 8 is a partially cross-sectioned view of a means of humidifying the valves of the bags;
- fig. 9 is the scheme of a high precision liquid dosing means;
- fig. 10 is a lateral schematic view of the filling portion of the actuating machine, incorporating the said dosing means of fig. 9;
- fig. 11 is a lateral view of an arrangement of the total print station (2);
- fig. 12 is an axonometric view of the valve welding station 5b;
- fig. 13 is an axonometric view of the final welding and molding block 5d, 5e.

With reference to figs 1 and 2 the system according to the invention is substantially representable with at least 5 stations, each involving one or more treatments.

In particular block 1 shows the stage, respectively the supplying station for the feeding of the film F from a reel B; the dashed rectangles show the possibility of placing in station 1 at least a second reel B' in parallel to the first reel B and of the same width as that, or else a reel B'' of a width n times the width of B or B'. Associated with the unwinding reel RS is a means for tension adjustment bearing a braking means DF.

According to another aspect of the invention block 2 shows a station of total printing TP on line (2a) followed by the accumulation (2b) of the thus completely printed film on line. The TP station now includes a hot printer that uses a hot-press as the impression means and that lays on the bag, from a pigmented film, the characters placed on a cliché. The station TP is preset to obtain the printing of the prescription, the lot number and the data of the daily production. Furthermore through the print menu it is possible to set up the bag format (from 50 cc to 5,000 cc), the temperature and speed and all the numerous parameters needed for the printing of the bag itself.

Block 3 shows the washing station phase that now consists of a single dry washing stage, there being no contact with liquids and supports. One of the preferred washing means is represented in figs 2B and 2C. It is formed by two superimposed chambers 101 and 102 with a central slot for the printed film FST

that is suspended and subjected to filtered air AF flowing in from three nozzles 103, 104 and 105, the said air flowing out through nozzles 106, 107 and 108 after having flowed over, and hence washed, particles and impurities from the printed film FST as shown in fig. 2C. In the case of using more reels B, B' etc. of equal length, or a reel B" of a width n times greater than the previous ones, the stations 2 and 3 are able to operate contemporarily on film plurality.

Block 4 shows the treatment of the printed film on line and dry washed, FSTL, in only four subphases that now foresee: accumulation (4b) of FSTL, gimballing alignment (4d), folding (4e), and towing (4f).

In the system according to the present invention there has been the advantageous elimination of not only the drying phase (4a) (due to dry washing) but also the phase (4c) of sterilization with ultraviolet rays UVA of the US Patent N° 4,456,813. As can now be seen the station is extremely more compact, efficient and reliable. The few means for performing these operations are thus the rollers (4b), (4d), (4e, 4e' with the folding prism PR) and (4f), there having been eliminated the old squeezing rollers (4a) and the UV plate associated with the rollers (4c).

The functioning of the alignment rollers (4b), the folding prism PR inserted between the rollers (4e) and (4e') and, lastly, the towing roller (4f) cooperating with the second folding roller (4e') is now faster and safer (also because there are no stops and interruptions in the new, only four-phase, station 4). Station 5 can now be considered "revolutionized" compared with that of our previous US patent N° 4,656,813. In fact in station 5, bag formation by vertical and horizontal welding

and application of valve(s) and suspension rings, there are now found only substations of longitudinal (vertical) welding (5a) and valve application (5b).

Figs 4 and 5 show two valve structures of the types EMO-LUER and TWIN VALVE. They consist of a cap T, a valve core CV, a rubber plug GP and two cavities CA1 and CA2. In the "TWIN" valve TO indicates the part to be removed at the moment of using the product, guaranteeing the sterility of the product contained within, ZF indicates the twist-off fracture zone. The EMO-LUER valve of fig. 5 consists of the valve core EPO-L, the rubber plug GP, the cap TT, the perforator P and the warranty seal SG that will be broken at the moment of use; OR indicates the sealing gasket. These valves are in themselves already known for example from the Applicant's US Patent N°4,467,003. Shown in fig. 6 is a bag SA with a TWIN-VALVE valve TV at a transverse extremity, and a suspension hole in the opposite wall. Shown in fig. 7 is a bag SA with an EMO-LUER valve (VEM) on the longitudinal side and with a suspension ring AS on the other longitudinal side.

Characteristically station 5 now also comprises: x) a vibrator (5b1) for feeding the valves and, according to the most notable aspect of the invention, y) a spray wetting-means (5b2) for valve cavities; z) a means (5b3) for the detection and control of the wetting; j) a means (5c) for making a bag suspension hole; and w) a means (5f) for the application of a suspension ring (in addition to, or as an alternative to, the said hole), including also a vibrator (5f1) for the supplying of the said ring.

According to an aspect of the invention the valve welder is an ultrasound one with open ring control of position and approach speed. For such a purpose the original

welding system according for example to the US Patent N° 4,656,813 has been greatly improved by the introduction of a continuous checking of the position and speed of the welding head (5b) ("sonotrode") during its approach to the anvil (represented by dashes). Fig. 12 shows the relative block (5b) comprising a position transducer (81), a cylinder (82), a slide (83), the sonotrode (84), and a transducer (85). With an algorithm of the PID type sampled to a thousandth of a second, an optimization was carried out of the speed and the acceleration (deceleration) of the sonotrode/anvil impact, the aim being to make the whole welding operation as soft as possible (and hence reliable).

In a further aspect of the invention the dosing of the filling liquid RIEM is done with very great precision due to a station SP, substantially automatic, comprising at least electropneumatic valves (60) and (62) fed by (61) and a processing switchboard (63). The dosing valve has a double electropneumatic thrust and permits the operating (opening/closing) of the dosage means in a time of 3 to 5 thousandths of a second, allowing a precision of +/- 1cc per dosage quantity.

In the preferred embodiment the means is controlled by the number of impulses coming from a lobed flowmeter with Halls effect. Fig. 10 shows the arrival point AIC of the tubular feeding connection from the solution (not represented), the dosing valves of fig. 9, the broadened extremity EA of the supply tube TE within a bag SA in the filling phase, followed by the next bag SAC (also not yet sealed at the top, still to be filled).

Still another characteristic of the invention lies in the shaping of the bags (contemporarily with horizontal welding), through the regulation and control of the temperature of two mobile bars (71), (73) (fig. 13) that are heated by highly

efficient electric heating elements, and able to compress, weld and thermoform the bags, eliminating any possible ears. Besides the hot vulcanized bar (71), the means of fig. 13 includes a cold bar contrasting the cutting edge (72), the second hot forward bar (73); a cutting edge support (74) and a cold support bar of the cutting edge (75).

Again use is made of a PID (Proportional, Integral Derivative) type algorithm, ad hoc modified to optimize temperature control, for example on twelve interlaced points. The cooling of the welding follows immediately through the action of cooled bars (e.g. of the type 72, 75 of fig.13) that, besides cooling and blocking the welding folding process, cuts the bags themselves to measure.

As a notable aspect of the invention the humidification of the cavities CA1 CA2 of either the EMO-LUER or TWIN VALVE of figs 4 and 5 can be carried out in various ways, for example with the means of fig. 8, comprising a valve V1, a fluxstate FLU, a nebulization nozzle US, a piston PA to move the US served by a sensor SEP, a bridging circuit for the observation of the electric conductability in the already wet cavity for the controlling of the correct humidification, and a discharge channel for the wetting liquid CSLB.

Even though the invention has been described with reference to the embodiment forms represented in the accompanying drawings it is obvious that it is not limited to these embodiments but is susceptible to all the variants, modifications, substitutions and such like that, being within the reach of the person skilled in the art, fall naturally within the spirit and scope of the following claims. In fact the described means of dry washing, total printing, humidification etc. can be substituted by equivalent commercial means. Furthermore the system according

to the invention foresees the possibility not only of welding one or more valves onto the same bag but also of working on two series of bags (odds and evens) and of applying a type of valve, a ring or a suspension hole on the odd and even bags alternatively. The film and pellicle F (fig. 1) forming the bags (SA with valves and suspension means) are preferably multilayer, consisting of (co)-polymers of laminated olefins, amides, esters etc. (US patent N° 4,326,574), but better still coextruded, particularly those according to the Applicant's demands for European patent N°0658421 and International patent WO 95/16565.

Indeed optimal results have been obtained with coextruded film based on two external layers (homogeneous chemically) of ethylene copolymers (PE) - propylene (PP) that themselves differ only in the PE content, or of two chemically diverse layers e.g., polyethylene/polypropylene. The adhesion of the two layers is ensured by an appropriate coextruded binding, also polyolefinic. By cautiously choosing the composition of the external layers, the binding and hence the adhesion between the said layers, and any possible temperature difference between the welding bars etc. bags can be obtained with optimal values of welding resistance, resistance to shocks particularly dropping, transparency, sterilizability etc., etc.. The coextruded films can have additional layers, these also being coextruded or even laminated onto three-layer film (two external layers and that of the binding).

CLAIMS

- 1) A system for the forming and filling of flexible plastic-material containers, in particular sterilizable bags containing solutions for administration, infusion type solutions, including at least the phases of: - feeding a film or pellicle, preferably multilayer, from at least one reel; - printing, washing, winding the said printed material; - aligning and folding the said printed and washed film; - welding the film folded first in one direction, typically longitudinally or vertically; - supplying and applying valves onto the surface of the folded and welded film; - filling the bag; - effecting a second welding in a second direction, typically transverse or horizontal; - cooling and cutting the bags for sending to overwrapping and sterilization; the system being characterized by the fact that the number of steps or abovementioned phases is reduced, carrying out in particular: - a total printing (TP = total print) of the film as it winds off the supplying reel(s); - a dry cleaning of the printed film; - a gimballed aligning of the printed and washed film to be folded; - a hot-bar longitudinal welding (vertical) of the folded film; - application of the valve(s) by welding, controlling, by means of algorithm, the speed and position of the welding head during its approach to the anvil, the said valve(s) having undergone a humidification treatment of the cavity; - shaping the bags using algorithm-regulated hot tools; high precision dosage of the filling liquid
- 2) System according to claim 1, characterized by the fact that to subject the cavities (outside the bag and having no contact with the filling solution) to humidification use was made of a means to dose the liquid as a function of the cavity volumes themselves, and tools (5b3) to ascertain the wetting taking place, making it

possible to sterilize the cavities of the valve(s) in times and with procedures substantially equal to those of the bag sterilization

- 3) System according to claim 2, characterized by the fact that the wetting is effected downstream from a vibrator (5b1) associated with feeding the valves to the station (5b) for their welding onto the body of the bag, the means (5b3) for controlling the wetting of the cavities of the said valves being placed downstream from the wetting tools
- 4) System according to claims 2 and 3, characterized by the fact that the wetting liquid is chosen from among distilled water, physiological solutions and hydrogen peroxide
- 5) System according to claim 4, characterized by the fact that use is made of hydrogen peroxide to sanitize and detect the electric conductability in the cavities
- 6) System according to the preceding claims, characterized by the fact that the humidification apparatus (5b2) includes, in addition to the source of sterile liquid, a dosing valve (70) and a flusstate (71), outside a means that includes a nozzle that is moved by a double-effect piston controlled by a sensor, and that is supplied with a lance for penetration into the valve cavities, the discharged sterile liquid being detected by a circuit with electric bridging
- 7) System according to claim 1, characterized by the fact that the total stamp (total print, TP) in line on the film as it unwinds from the feeding reel(s) is made with a hot printer that uses as the impression means a hot press, depositing onto the bag, due to a pigmented film, the characters put on a cliché

- 8) System according to claims 1 and 7, characterized by the fact that the film, stamped/printed in line, is dry cleaned with purified air and, after accumulation, undergoes a gimballed alignment
- 9) System according to claim 7, characterized by the fact that a ring for suspension is welded onto the bag or, as an alternative, a suspension hole (FOS) is made
- 10) System according to the preceding claims, characterized by the fact that the liquid filling the bag is dosed with great precision in a station that includes in the inlet a contribution regulation valve (51), a constant pressure valve (52), a turbine flowmeter (53), that feeds the valve (54) with a true and proper washing of the solution inside the bag, still not welded transversely, the said valve having a double electropneumatic boost and the control being carried out by the number of impulses coming from a lobed flowmeter of Hall effect.
- 11) System according to at least one of the preceding claims, characterized by the fact that contemporary shaping at the transversal welding of the bags is carried out with two mobile bars heated by electric resistances of high output with temperature control on many points, preferably twelve interconnecting points, the cooling being effected by two mobile cold bars that, as well as cooling and blocking the folding process of the welding, contain means for the cutting and separation of the bags
- 12) System according to at least one of the preceding claims, characterized by the fact that the blocking of the valve welding is done with a means that includes substantially a transducer of position, a cylinder, a slide, a sonotrode and a piezoelectric transducer.
- 13) System substantially according to what described and shown.

For the Applicant: Bieffe Medital S.p.A.

The Representative: Dr. Ing. Italo INCOLLINGO